

- 12 -

Claims

1. Process for preparing a solid pharmaceutical composition of perindopril or a salt thereof, comprising
  - (i) dry mixing of perindopril or a salt thereof with at least one inorganic carbonate, at least one carrier, and optionally other components, and
  - (ii) dry processing of the mixture obtained in step (i) to the desired solid form.
2. Process according to claim 1, wherein the composition comprises the tert.-butyl amine salt of perindopril.
3. Process according to claim 1 or 2, wherein the inorganic carbonate is sodium carbonate, sodium hydrogen carbonate, magnesium carbonate, calcium carbonate or calcium hydrogen carbonate.
4. Process according to any one of claims 1 to 3, wherein the molar ratio of perindopril or a salt thereof to inorganic carbonate is 1 to 0.1-0.9 and preferably 1 to 0.50-0.83.
5. Process according to any one of claims 1 to 4, wherein the carrier is microcrystalline cellulose, lactose or a mixture thereof.
6. Process according to claim 5, wherein the microcrystalline cellulose has a moisture content of 0.3 to 5.0 % by weight, preferably 0.3 to 1.5 % by weight.
7. Process according to claim 5 or 6, wherein the lactose is anhydrous lactose.

- 13 -

8. Process according to any one of claims 1 to 7, wherein step (ii) is effected by direct compression of the mixture.
9. Process according to any one of claims 1 to 8, wherein the composition also comprises indapamide or a hydrate thereof.
10. Process according to claim 9, wherein the hydrate is indapamide hemihydrate.
11. Process according to claim 9 or 10, wherein 90 % of the particles of indapamide or a hydrate thereof have a size of less than 80 $\mu$ m.
12. Process according to claim 11, wherein 90 % of the particles of indapamide or a hydrate thereof have a size of less than 70 $\mu$ m.
13. Solid pharmaceutical composition of perindopril or a salt thereof, comprising
  - (a) perindopril or a salt thereof,
  - (b) at least one of microcrystalline cellulose having amoisture content of 0.3 to 5.0 % by weight and anhydrous lactose,
  - (c) optionally at least one inorganic carbonate, and
  - (d) optionally other components.
14. Composition according to claim 13, wherein the molar ratio of perindopril or a salt thereof to inorganic carbonate is 1 to 0.1-0.9 and preferably 1 to 0.50-0.83.
15. Composition according to claim 13 or 14, wherein the microcrystalline cellulose has a moisture content of

- 14 -

0.3 to 1.5 % by weight.

16. Composition according to claim 15 which further comprises indapamide or a hydrate thereof.
17. Composition according to claim 16, wherein 90 % by volume of the particles of indapamide or a hydrate thereof have a size of less than 80 $\mu$ m.